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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,657	08/25/2006	**Jan Mollenhauer**	5976-0111PUS1	1500

2292 7590 11/26/2010

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

NOTIFICATION DATE	DELIVERY MODE
11/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,657	MOLLENHAUER ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26July2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,35,37 and 40-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *40-60 and 64-66* is/are allowed.

6)☒ Claim(s) *31-63 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 July 2010 has been entered.

It is noted that the status of claim 52 is listed as (Currently Amended). It should be listed as (Previously Presented) because the amendment of the claim was presented in applicants' submission of 1 October 2009.

New claim 67 has been added.

2. Claims 31, 35, 37 and 40-67 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 31, 35, 37 and 61-63 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment or prevention of all diseases caused by all agents, is maintained for reasons of record.

Applicants argue that the Examiner seems to require a showing of efficacy of *in vivo* administration of DMBT1. Applicants argue that the specification teaches the presence of expressed DMBT1 decreased the sensitivity to an inflammatory agent, and that the Declaration of Dr. Mollenhauer shows *in vitro* administration of DMBT1 decreases inflammatory factors. Therefor, other individuals have concluded that administration of DMBT1 would be effective to treat diseases.

The examiner has considered applicants' arguments, but does not find it persuasive for reasons of record. While the specification and the Declaration of Dr. Mollenhauer do teach *in vitro* identification of DMBT1 characteristics, there is no evidence that DMBT1 would fulfill the requirements of the instant claims, i.e., treat or prevent diseases *in vivo*.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Newly added claim 67 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DMBT1 identification and purification, production of DMBT1 knockout mice and *in vitro* binding studies, does not reasonably provide enablement for treatment or prevention of ulcerative colitis caused by all agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – methods of treating or preventing ulcerative colitis caused by an agent possessing $\geq$1 accessible sulphate and/or $\geq$1 accessible phosphate group

comprising administering to a patient a therapeutically effective amount of a polypeptide comprising the sequence of SEQ ID NO:1, or a functional fragment or derivative thereof, or of a nucleic acid comprising the sequence of SEQ ID NO:2, or a functional fragment or derivative thereof.

The state of the prior art as evidenced by applicants specification, page 2, lines 7-21, indicates that DMBT1 (SEQ ID NO:1) is a salivary agglutinin and is known to interact with bacterial and viral pathogens (Prakobphol et al, *J. Biol. Chem.*, 275:39860-39866, 2000).

However, there is a lack of predictability in the art that administration of DMBT1 can treat or prevent ulcerative colitis caused by all agents.

The amount of direction or guidance present in the instant specification is insufficient support for the extremely broad scope of the instant claims. While the specification hypothesizes that DMBT1 may treat and prevent diseases, the only working examples are directed to identification, purification and *in vitro* binding of DMBT1 and the production of DMBT1 knockout mice. There are no working examples of treatment by administration of DMBT1.

Thus, the instant claims constitute merely an invitation to experiment without a reasonable expectation of success.

Conclusion

5. Claims 31, 35, 37, 61-63 and 67 are rejected.

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Larry Helms, at (571)272-0832.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 23, 2010